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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,710	02/21/2004	Jindong Sun	38-21(52743)B	5894
27161 7590 02/21/2007 MONSANTO COMPANY 800 N. LINDBERGH BLVD. ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA) ST. LOUIS, MO 63167			EXAMINER KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/21/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/783,710

Applicant(s)

SUN ET AL.

Examiner

David H. Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1 and 5-13, in the reply filed on 21 November 2006 is acknowledged. The traversal is on the ground(s) that the claims have been amended and thus the restriction is now moot. Given Applicants' amendments to the claims to read on the invention of Group I, the Examiner concurs that the restriction is now moot.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

### ***Sequence Rules***

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825. Specifically, Figure 1 of the Specification. If the sequences are supported by the Sequence Listing, the Brief Description of the Drawings on page 3 can be amended, otherwise Applicant must submit a CRF copy and paper copy of the Sequence Listing, a statement that the content of the paper and computer readable

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copies are the same and where applicable include no new matter as required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(d), as well as an amendment directing its entry into the specification.

Failure to comply with these requirements in response to this Office Action will be considered non-responsive to this Office Action.

***Claim Objections***

4. Claims 5, 9 and 11-13 are objected to because of the following informalities:

Claim 5, "Transgenic" should read -- The transgenic -- because it is further limiting claim 1.

Claim 9, "A method" should read -- The method -- because it is further limiting claim 8.

Claims 11-13, "A hybrid" should read -- The hybrid -- because they are further limiting a previous claim.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1 and 12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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At claim 1, line 3, "and protein which confers" is indefinite because it is unclear what the metes and bounds of the limitation are. Amending the phrase to read -- and a protein, which confers -- would obviate this rejection.

At claim 12, line 3, "insect resistance" lacks proper antecedent basis in claims 10 and 11. Appropriate correction is required.

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 and 5-13 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a transgenic seed and plant, a method of improving the yield of a crop and hybrid corn comprising a recombinant DNA encoding a transcription factor comprising the consensus amino acid sequence of SEQ ID NO: 11.

Applicants describe three amino acid sequences SEQ ID Nos: 1, 2 and 3 in the instant specification but none of said amino acid sequences comprise the consensus amino acid sequence of SEQ ID NO: 11. Applicants describe transforming *Arabidopsis*, soybean and corn with a recombinant DNA encoding SEQ ID NO: 2, wherein said recombinant DNA produces increased tolerance to water deficit (see pages 12-13 of the instant specification).

Applicants fail to adequately describe the genus of recombinant DNAs encoding a transcription factor comprising the consensus amino acid sequence of SEQ ID NO: 11. Hence, it is unclear that Applicants were in possession of the invention as broadly claimed.

The art teaches that transcription factors comprising the AT-hook motif have widely variant functions, and that the AT-hook motifs seem to be auxiliary elements necessary for cooperation with other DNA-binding activities in the same or different proteins (Aravind *et al* 1998, Nucleic Acids Research 26(19): 4413-4421, see page 4413, right column, and Table 1 at pages 4415-4417). Applicants do not describe SEQ ID NO: 1-3 as describing transcription factors with a common specific function, specifically capable of increasing tolerance to water deficit. In addition, since the asserted consensus amino acid sequence of SEQ ID NO: 11 appears to be directed to a portion of a DNA binding site, and not specifically to a consensus amino acid sequence that describes a common specific function, the instant invention does not appear to be adequately described as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs,

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defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence

See *Vas-Cath Inc. v. Mahurkar* 1991 (CA FC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

9. Claims 1 and 5-13 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants claim a transgenic seed and plant, a method of improving the yield of a crop and hybrid corn comprising a recombinant DNA encoding a transcription factor comprising the consensus amino acid sequence of SEQ ID NO: 11.

Applicants teach three amino acid sequences SEQ ID Nos: 1, 2 and 3 in the instant specification but none of said amino acid sequences comprise the consensus amino acid sequence of SEQ ID NO: 11. Applicants teach transforming *Arabidopsis*, soybean and corn with a recombinant DNA encoding SEQ ID NO: 2, wherein said recombinant DNA produces increased tolerance to water deficit (see pages 12-13 of the instant specification).

Applicants do not teach how to make and use the genus of recombinant DNAs encoding a transcription factor comprising the consensus amino acid sequence of SEQ ID NO: 11.

*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.



Applicants provide limited guidance on how to make and use recombinant DNAs encoding a transcription factor comprising the consensus amino acid sequence of SEQ ID NO: 11. The art teaches that transcription factors comprising the AT-hook motif have widely variant functions, and that the AT-hook motifs seem to be auxiliary elements necessary for cooperation with other DNA-binding activities in the same or different proteins (Aravind *et al* 1998, *Nucleic Acids Research* 26(19): 4413-4421, see page 4413, right column, and Table 1 at pages 4415-4417). Hence, given the nature of the invention, one of skill in the art at the time of Applicants' invention could not predict what function an encoded transcription factor comprising the consensus amino acid sequence of SEQ ID NO: 11 would produce in a transformed plant. Applicants do not teach SEQ ID NO: 1-3 as comprising the consensus amino acid sequence of SEQ ID NO: 11 and capable of increasing tolerance to water deficit. In addition, since the asserted consensus amino acid sequence of SEQ ID NO: 11 appears to be directed to a portion of a DNA binding site, and not specifically to a consensus amino acid sequence that teaches a common specific function, the instant invention does not appear to adequately teach one of skill in the art how to make and use the invention as broadly claimed. Given the limited guidance provided by Applicants, the nature of the invention, the unpredictability of the art at the time of Applicants' invention it would have required undue trial and error experimentation by one of skill in the art to make and use the invention as broadly claimed.

**Conclusion**

10. The claims are free of the prior art which does not teach a transgenic seed and plant, a method of improving the yield of a crop and hybrid corn comprising a recombinant DNA encoding a transcription factor comprising the consensus amino acid sequence of SEQ ID NO: 11.

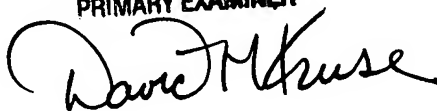
11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

DAVID H. KRUSE, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink that reads "David H. Kruse". The signature is written in a cursive style with a large, looping "D" and "K".

David H. Kruse, Ph.D.  
15 February 2007

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13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.